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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,988	07/05/2001	Yuta Nakai	210669US0	1677

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,988

Applicant(s)

NAKAI ET AL.

Examiner

Maria B. Marvich, PhD

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2005 and 28 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6 and 7 is/are rejected.
- 7) ☒ Claim(s) 8 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 7/25/05
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This is a supplemental office action to correct errors in the office action mailed 6/17/05 mailed in response to an amendment filed 11/23/04 and 3/28/05. Claims 1-3, 6-8 and 10 have been amended. Claims 4, 5 and 9 have been cancelled. Claims 1-3, 6-8 and 10 are pending in this application.

A substitute specification was submitted with the amendment filed 11/23/04 and erroneously not entered. The substitute specification filed 11/23/04 has been entered.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. The new grounds of rejection herein were necessitated by amendment and, therefore, this action is final.

Claim Rejections - 35 USC § 112

Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in the office action in the office action mailed 4/9/03 and 8/9/04.**

Applicants claim a genus of microorganisms constructed from a parent strain that has a respiratory pathway of high-energy efficiency and a respiratory pathway of low energy efficiency. The genus comprises microorganisms that are mutant or genetic recombinant having

Art Unit: 1633

either or both an enhanced respiratory chain pathway of high-energy efficiency and a deficient respiratory chain pathway of low energy efficiency.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

The instant invention recites as an essential element for the production of target substances, improved microorganisms obtained from parent strains that are engineered to contain altered high and low energy efficiency genes of the respiratory chain pathway or both. The structure of a species is disclosed as the specification discloses that the *E. coli* strains W3110 and VKPM B-3996 are parental strains for the construction of the overproducing cyo strains and deficient NDHII strains. As well, applicants disclose that Corneyform bacteria comprise high and low energy efficiency genes, bcl complex and cytochrome bd. The specification does not disclose relevant identifying characteristics of the two bacteria or nature of the mutation or genetic engineering sufficient to describe the steps to attain the mutant strains with the derived high energy or low energy efficiencies in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Nor does the specification disclose a correlation between the mutations or genetic changes in the exemplified cell, *E. coli*, and those required in other organisms to produce the necessary changes in the respiratory pathway for use in the claimed invention. For inventions in an unpredictable art,

Art Unit: 1633

adequate written description of a genus cannot usually be achieved by disclosing only one species within the genus. Furthermore, the specification and the prior art has not established a strong correlation between the structure of mutated or genetically altered enzymes and their function in altering respiratory pathways in the organism and one skilled in the art cannot predict with a reasonable degree of confidence the structure of the claimed invention from the recitation of its function. Therefore, the skilled artisan cannot conclude that the applicant was in possession of the claimed invention.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 112, first paragraph for lack of written description on page 6 of the amendment filed 11/23/04. Applicants argue that the claims have been amended to specify the specific enzymes of either the high energy or low energy respiratory pathway and have thus overcome the rejection.

Applicants' arguments filed 11/23/04 have been fully considered but they are not persuasive. The rejection of the instant claims under 112, first paragraph for lack of written description has not been overcome by the amendment to the claims. The rejection of the claims for lack of written description still stands, as applicants have not described the genus with such detail that a person of skill in the art would recognize that applicants were in possession of the invention. The instant claims are drawn to any microorganism obtained from parent strains that are engineered to contain altered high and low energy efficiency genes of the respiratory chain pathway. Applicants have only reduced to practice and demonstrated possession of a single species, a mutant strain of *E. coli* in which the strain has been manipulated to over express *cyo*

and is deleted of NDH-II. Applicants have also indicated the *Corneyform* bacteria comprise genes of high and low respiratory pathways that are related to those of *Escherichia*. However, applicants have not demonstrated in such detail the method of generating the mutant strain or the mutated enzymes such that one of skill in the art would recognize the broad genus of any microorganism obtained from any parent strains that are engineered to contain altered high and low energy efficiency genes of the respiratory chain pathway. Furthermore, applicants have not provided in sufficient details the relevant identifying characteristics of the mutant overproducing cyo strains and deficient NDHII strains such that a person of skill in the art would recognize that applicants were in possession of the genus of microorganisms comprising mutations or alterations in the high and/or low energy efficiency pathways.

Conclusion

Claims 1-3, 6 and 7 are rejected.

Claims 8 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1633


the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1633

August 6, 2005


JAMES KETTER
PRIMARY EXAMINER